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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,635	08/03/2001	James C. Sacchetti	TAMK:247---12740.0247.NP	5795

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EXAMINER
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LY, CHEYNE D

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/921,635

Applicant(s)

SACCHETTINI ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on June 14, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-16,21,22,31 and 35-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-20,23-30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicants' arguments filed June 14, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The withdrawal of claims 1-16 and 35-45 has been acknowledged.

3. It is re-iterated that claims 21, 22, and 31 have been withdrawn due to the elected group not being directed to the elected species.

4. Claims 17-20, 23-30, and 32-34, 3-nitropropionate, compounds selected by design starting from a known inhibitor, and the competitive inhibitor, are examined on the merits.

### **CLAIM REJECTIONS - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the

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time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 17-20, 23-30, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (US 5,856,116 A) in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Britton et al. (April 2000) in combination with McKinney et al. (US 6,387,694 B1).

8. This rejection is maintained with respect to claims 17-20, 23-30, and 32-34, as recited in the previous office action mailed September 22, 2003.

#### **RESPONSE TO ARGUMENTS**

9. Applicant's argument that Wilson et al. discloses a method for designing, select and synthesize inhibitory compounds is specific to ICE, but not to ICL as required by the claimed invention has been fully considered. It noted that the disclosure of Wilson et al. being directed to ICE has been discussed in the previous Office Action, mailed September 22, 2003. Further, the specific limitations of atomic coordinates and data directed to Figures 5-7 in this instant case do not distinguish the invention from the prior art in terms of patentability because they are descriptive nonfunctional subject matter as discussed below.

10. Applicant's argument that "the structures discussed by Britton are disordered in the active site region...The Britton structures therefore have little utility for drug design" has been fully considered and found to be unpersuasive due to Applicant's argument being an unsubstantiated opinion. Applicant has not provided any factual support via pointed to disclosure in the instant specification, or cited references for the above argument.

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11. Applicant's argument that the recitation of nitropropionate and itaconate by Britton et al. does not "impact claims 26, 28, and 34" because said "claims are directed to a method of identifying an inhibitor, as recited in independent claim 20. The presence in the art of known inhibitors does not impact a novel method of identifying previously unknown inhibitors." It is noted that claims 20, 26, 28, and 34 do not recite the limitation of "identifying previously unknown inhibitors." It is the disclosure of Wilson et al. in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Britton et al. in combination with McKinney et al. as a whole which makes the claimed invention obvious over the cited the prior art.

12. Further, it is noted that the claims are given their broadest reasonable interpretation consistent with the specification. However, the instant claims are not limited to the critical steps as argued by Applicant. As cited by the MPEP, the court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim, to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim. (See also In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (MPEP §2111 [R-1])).

13. Applicant's argument that "McKinney does not provide enough information to actually identify inhibitors" has been fully considered and found to be unpersuasive due to Applicant's argument being an unsubstantiated opinion. McKinney et al. discloses the use of

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the atomic coordinates produced from *M. tuberculosis* isocitrate lyase for identifying and designing ICL inhibitors (column 8, lines 55-67, to column 9, line 2). It is the disclosure of Wilson et al. in view of *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Britton et al. in combination with McKinney et al. as a whole which makes the claimed invention obvious over the prior art.

14. Applicant argues that Examiner's analysis as directed to *In re Gulack* is not applicable to the presently pending claims. Specifically, Applicant argues that the claimed invention is directed to "a method of identifying inhibitors or compounds to bind to specific proteins, and...rely on the structural coordinates that Applicant has discovered." Applicant's argument has been fully considered and found to be unpersuasive due to the claims do not recite any steps for "inhibitors or compounds to bind to specific proteins." It is noted that the claims recite steps for identifying an inhibitor by analyzing (obtaining and defining) atomic coordinates of ICL. Further, the "fits" limitation is merely the rearrangement of atomic coordinates which has been considered to be to be nonfunctional descriptive material. The limitations argued by Applicant to be absent from the cited prior art are not present in the instant claims; therefore, the citation of said limitations are not required.

15. Applicant argues that "regardless of how motivated one of skill in the art might have been, it would have been impossible for him to design such inhibitors without the structural coordinates that are provided by the present invention." Further, Applicant points to Jan Drenth to support that the structural coordinates provided by the present invention are not easily obtained. Applicant's arguments have been fully considered and found to be unpersuasive. It is noted that the pointed to citation of Jan Drenth supports that because of

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the protein crystallization method is in essence a trial-and-error process, the results from said process are usually unpredictable. However, Jan Drenth does not disclose that it is impossible to generate protein structural coordinates. Further, the basis for citing Wilson et al. in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Britton et al. in combination with McKinney et al. in the instant prior art rejection is not that one of ordinary skill in the art would be able to design inhibitors of microbial ICL without the structural coordinates of said ICL. However, the basis for the instant prior art rejection is that the instant method uses atomic coordinates and data directed to Figures 5-7 to merely store said atomic coordinates so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer. Then, the atomic coordinates data is considered to be descriptive material which alone does not impart functionality either to the data as so structured, or to the computer. The specific limitations of atomic coordinates and data directed to Figures 5-7 in this instant case do not distinguish the invention from the prior art in terms of patentability because they are descriptive nonfunctional subject matter as supported by In re Gulack. Therefore, it is the disclosure of Wilson et al. in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Britton et al. in combination with McKinney et al. as a whole which makes the claimed invention obvious over the prior art.

**REJECTION RE-ITERATED**

16. Wilson et al. discloses a method for identifying inhibitors having said inhibitor binding to the active site of ICE as defined by the structure coordinates of said ICE (column 8, lines 41-43, lines 51-55, and column 9, lines 20-25), as in instant claims 17-19.

17. The space-filling model of ICE discloses a known inhibitor such as tetrapeptide aldehyde inhibitor bound (contacting) the said ICE (Figures 2 and 4), as in instant claims 20, 23-25.

18. A “competitive inhibitor” is one that inhibits ICE activity by binding to the same kinetic form, of ICE, as its substrate binds (column 5, lines 50-54), as in instant claim 30. Wilson et al. further discloses the limitation of synthesizing inhibitors (column 2, lines 56-61), as in instant claims 29, 32 and 33. It is well known in the art a competitive inhibitor binds to a active and changes the conformation of said active site from open to closed conformation (Campbell, page 107, Figure 6.17).

19. Even though the method disclosed by Wilson et al. does not specify that the atomic coordinates and data directed to Figures 5-7, the specific limitations of atomic coordinates and data directed to Figures 5-7 in this instant case do not distinguish the invention from the prior art in terms of patentability because they are descriptive nonfunctional subject matter.

20. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability. Also, the MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(b)). Specific to the instant case, atomic



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coordinates and data directed to Figures 5-7 are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

21. Britton et al. discloses the crystal structure and active site location of isocitrate lyase from the fungus *Aspergillus nidulans* (Abstract et al.) and nitropropionate and itaconate (second antimicrobial) as inhibitors of ICL from mycobacteria for controlling growth of said mycobacteria (page 350, column 1, lines 1-17), as in instant claims 26, 28, and 34.

22. McKinney et al. discloses the use of the atomic coordinates produced from M. tuberculosis isocitrate lyase for identifying ICL inhibitors (column 8, lines 55-66), as in instant claim 27.

23. Wilson et al. a method of designing improved enzyme inhibitors. In re Gulack defines nonfunctional descriptive material, as when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability. An artisan of ordinary skill in the art would have been motivated to partake the concept emphasized by Wilson et al. and improve on the method by using the method of Wilson et al. for designing inhibitors to isocitrate lyase as taught by Britton et al. and McKinney et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of designing inhibitors to isocitrate lyase as taught by Wilson et al., Britton et al., and McKinney et al.

### CONCLUSION

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26. This application contains claims 1-16, 21, 22, 31, 35-45 are drawn to an invention nonelected with traverse, filed August 01, 2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

27. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

28. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent

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number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

29. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly

9/1/04

*Ardin H. Marschel 9/3/04*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER